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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,972	03/01/2002	Robert M. Hoek	DX0936KB	1945

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DNAX Research, Inc.
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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,972	HOEK ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 - 20 are pending.

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. The following is noted: Independent Claims 1 and 16 include a recitation of a method of "modulating" trafficking or activation of leukocytes. Dependent claims 6 and 17 recite that modulating is inhibiting, whereas dependent claims 11 and 19 recite that modulating is enhancing. These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ structurally distinct agents to accomplish these mutually exclusive endpoints. Consequently, the claims have been limited to either a method relating to inhibiting, or a method relating to enhancing, irrespective of the format of the claims.

Likewise, claims 1 and 16 recite methods administering an agonist or an antagonist of OX2. These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ structurally distinct agents to accomplish these mutually exclusive endpoints. Consequently, the claims have been limited to either a method relating to inhibiting, or a method relating to enhancing, irrespective of the format of the claims.

4. It is noted that claims 4, 9, and 14 recite a method of modulating the activation of lymphocytes in an animal which exhibits symptoms of one of a number of listed diseases. These diseases are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct

subject matter. Consequently, the restriction has been set forth for each disease as a separate group, irrespective of the format of the claims.

Restriction Requirement

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 4 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has an inflammatory condition, classified in Class 514, subclass 21.

II. Claims 1, 4 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has an infective condition, classified in Class 514, subclass 21.

III. Claims 1, 4 – 8, 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has a leukoproliferative condition, classified in Class 514, subclass 21.

IV. Claims 1, 4 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has a neurodegenerative condition, classified in Class 514, subclass 21.

V. Claims 1, 4 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has a post-traumatic condition, classified in Class 514, subclass 21.

VI. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has autoimmunity, classified in Class 514, subclass 21.

VII. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has atherosclerosis, classified in Class 514, subclass 21.

VIII. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has delayed hypersensitivities, classified in Class 514, subclass 21.

IX. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has skin grafting or a transplant, classified in Class 514, subclass 21.

X. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has spinal injury, classified in Class 514, subclass 21.

XI. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has stroke, classified in Class 514, subclass 21.

XII. Claims 1, 5 – 10, and 16 – 18, drawn to a method of inhibiting the function of leukocytes in an animal, using an agonist of OX2, where the animal has ischemia, classified in Class 514, subclass 21.

XIII. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where

the antagonist is an antibody to OX2, and where the animal has an inflammatory condition, classified in Class 424, subclass 130.1.

XIV. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is an antibody to OX2, and where the animal has an infective condition, classified in Class 424, subclass 130.1.

XV. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is an antibody to OX2, and where the animal has a leukoproliferative condition, classified in Class 424, subclass 130.1.

XVI. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is an antibody to OX2, and where the animal has a neurodegenerative condition, classified in Class 424, subclass 130.1.

XVII. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is an antibody to OX2, and where the animal has a post-traumatic condition, classified in Class 424, subclass 130.1.

XVIII. Claims 1 – 3, 5, 11 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is an antibody to OX2, and where the animal has wound healing, classified in Class 424, subclass 130.1.

XIX. Claims 1 – 3, 5, 11 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is

an antibody to OX2, and where the animal has clot formation, classified in Class 424, subclass 130.1.

XX. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is a mutein of OX2, and where the animal has an inflammatory condition, classified in Class 424, subclass 9.322.

XXI. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is a mutein of OX2, and where the animal has an infective condition, classified in Class 424, subclass 9.322.

XXII. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is a mutein of OX2, and where the animal has a leukoproliferative condition, classified in Class 424, subclass 9.322.

XXIII. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is a mutein of OX2, and where the animal has a neurodegenerative condition, classified in Class 424, subclass 9.322.

XXIV. Claims 1 – 5, 11 – 13, 15 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is a mutein of OX2, and where the animal has a post-traumatic condition, classified in Class 424, subclass 9.322.

XXV. Claims 1 – 3, 5, 11 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is

a mutein of OX2, and where the animal has wound healing, classified in Class 424, subclass 9.322.

XXVI. Claims 1 – 3, 5, 11 – 16, and 19 – 20, drawn to a method of enhancing the function of leukocytes in an animal, using an antagonist of OX2, where the antagonist is a mutein of OX2, and where the animal has clot formation, classified in Class 424, subclass 9.322.

6. Groups I – XXVI are different methods. The methods differ with respect to ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. This application contains claims (claim 5) directed to the following patentably distinct species of the claimed Inventions I - XXVI, wherein the sign or symptom is in:

(A) neural tissue,

(B) lymphoid tissue,

(C) myeloid tissue,

(D) pancreas,

(E) gastrointestinal tissue,

(F) thyroid tissue,

(G) muscle tissue,

(H) skin, or

(I) collagenous tissue.

These species are distinct because their structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claim 5, for example, is generic.

9. This application contains claims (claim 7) directed to the following patentably distinct species of the claimed Inventions I - XII, wherein the autoimmune disorder is:

(A) tissue specific autoimmunity,

(B) rheumatoid arthritis,

(C) multiple sclerosis, or

(D) vasculitis.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claim 7, for example, is generic.

10. This application contains claims (claims 10 and 18) directed to the following patentably distinct species of the claimed Inventions I - XII, wherein the administering is in combination with:

(A) an anti-inflammatory cytokine agonist,

(B) an anti-inflammatory cytokine antagonist,

(C) an analgesic,

(D) an anti-inflammatory agent, or

(E) a steroid.

These species are distinct because their structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claims 10 and 18, for example, are generic.

11. This application contains claims (claims 15 and 20) directed to the following patentably distinct species of the claimed Inventions XIII – XXVI, wherein the administering is in combination with:

(A) an angiogenic factor,
(B) a growth factor (FGF),
(C) a growth factor (PDGF),
(D) an antibiotic, or
(E) a clotting factor.

These species are distinct because their structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claims 15 and 20, for example, are generic.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Examiner
Art Unit 1644

September 7, 2004

PHILLIP GAMBEL, PH.D
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